K001203

MAY 2 6 2000

510(k) SUMMARY
OLYMPUS UM-2R/UM-3R ULTRASONIC PROBE

Device Name:	Olympus UM-2R / UM-3R Ultrasonic Probes and its ancillary equipment for female reproductive tract
Common / Usual Name:	Olympus Ultrasonic Probes
Classification Number & Classification Name:	Class II , 21CFR 892.1570 Diagnostic ultrasound transducer Class II, 21CFR876.1500 Endoscope and accessories
Predicate Devices:	Olympus EU-M30 (K951994) Olympus UM-2R / UM-3R (K944610) Olympus EU-M20 (K926514) Olympus EU-M3 (K882061)
Submitted By: (Contact Person)	Laura Storms-Tyler Olympus America Inc. Regulatory Affairs Two Corporate Center Drive Melville, NY 11747 (516) 844-5688
Summary Preparation Date:	July 31, 1998

Statement of Intended Use

The Olympus UM-2R and UM-3R Ultrasonic Probes have been cleared for use within the gastrointestinal tract in 510(k) #K944610.

The Olympus UM-2R and UM-3R Ultrasonic Probes have been designed for use in combination with Olympus Endoscopic Ultrasound System for intraluminal sonographic imaging of the female reproductive tract.

Device Description

In routine examination of the female reproductive tract, there are situations where the physician prefers to perform an intensive examination, observation, and diagnosis of the female reproductive tract. The conventional type hysterscope limits the physician's ability to access certain areas of interest. The UM-2R / UM-3R Ultrasonic Probes, when used with an endoscope offer transendoscopic access to the female reproductive tract. The 2.4 mm insertion tube of these probes

can be advanced through strictures and anatomical ducts. The Olympus Ultrasonic Probes to be used in conjunction with hysteroscope with a minimum capacity size 9Fr.. A probe-driving unit controls the rotation of the transducer.

The UM-2R and UM-3R probes produce a B-mode scans using the de-aerated water immersion method and offer 360 degree mechanical/radial scanning of the tissue under observation, The outer diameter of the insertion tube is 2.4 mm and the length is 2050 mm. Both probes incorporate similar design, construction, intended use, and method of operation. The only difference between these two probes is that the UM-2R probe operates at 12 MHz and is compatible with both Olympus EU-M30, EU-M20 and EU-M3 Endoscopic Ultrasound Systems, while the UM-3R probe operates at 20 MHz and is compatible with the EU-M30 and the EU-M20 Endoscopic Ultrasound System. The Olympus EU-M30 Endoscopic Ultrasound Center was cleared for marketing in 510(k) # K951994. The Olympus EU-M20 Endoscopic Ultrasound System was cleared for marketing in 510(k) # K926514 and EU-M3 Endoscopic Ultrasound System was cleared for marketing in the 510(k) # K882061.

All components and associated equipment of the UM-2R / UM-3R Ultrasonic Probes will be marketed non-sterile and can be reprocessed as described in the Instruction Manual.

Safety

The Olympus UM-2R and UM-3R Ultrasound Probes are designed, manufactured, and tested in compliance with International Standard IEC 60601-1. The ultrasound characteristics of Olympus UM-2R and UM-3R Ultrasound Probes meet the requirements of the FDA's 510(k) Diagnostic Ultrasound Guidance for 1993 and 1985.

When compared to the predicate devices listed in the "Regulatory History" portion of this section, except for intended use, neither ultrasound probe incorporates any significant change in method of operation, material, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Olympus Optical Co., Ltd.
C/O Laura Storms-Tyler
Olympus America, Inc.
Director, Regulatory Affairs and Quality Assurance
Two Corporate Center Drive
Melville, NY 11747

Re: K001203
Olympus UM 2R/3R Ultrasonic Probe and Associated
Ancillary Equipment for Female Reproductive Tract
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: April 3, 2000
Received: April 13, 2000

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Olympus EU-M30, EU-M20, and EU-M3 Endoscopic Ultrasound Systems, as described in your premarket notification:

Probe Model Numbers

UM2R
UM3R

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez (301) 594-1212.

Sincerely yours,

for David A. Segmon

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Ultrasound System: EU-M30

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	N/P									

N = new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: New Indications:Intraluminal imaging for female reproductive tract.

Previously cleared Indications: Intraluminal ultrasound for gastrointestinal tract and urological tract.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

E-3

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K001203

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Ultrasound System: EU-M20

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	N/P									

N = new Indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: New Indications: Intraluminal imaging for female reproductive tract.

Previously cleared Indications: Intraluminal ultrasound for gastrointestinal tract and urological tract.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use (Per 21 CFR 801.109)

Donald A. Legem

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K001203

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Ultrasound System: EU-M3

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	N/P									

N = new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: New Indications: Intraluminal imaging for female reproductive tract.

Previously cleared Indications: Intraluminal ultrasound for gastrointestinal tract and urological tract.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K001203

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Transducer
12 MHz
Catalog #
27023
Model UM2R

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	N/P									

N = new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: New Indications: Intraluminal imaging for female reproductive tract.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K001203

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	N/P									

Transducer
20 MHz
Catalog # 27024
Model UM3R

N = new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: New Indications: Intraluminal imaging for female reproductive tract.

Previously cleared Indications: Intraluminal ultrasound for gastrointestinal tract and urological tract.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

David G. Segerson

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K001203